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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
GIBBS, TERRA C	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 07/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/663,875	LIN ET AL.	
	Examiner	Art Unit	
	Terra C. Gibbs	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-57* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is a response to Applicant's Amendment filed May 15, 2006.

Claims 1-57 are pending in the instant application.

Claims 1-57 are subject to restriction as detailed below:

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 2-6, 8, 11, and 19, drawn to an isolated RNA comprising an intron RNA that is released in a cell thereby modulating the function of a target gene, wherein the isolated RNA does not contain a combination of a splice donor site that includes 5'-GU(A/G)AGU-3' and a splice acceptor site that includes 5'-CU(A/G)A(C/U)NG-3', and a cultivated cell thereof, classifiable in class 536, subclass 24.1.

II. Claims 9, 10, 12, 16, and 20, drawn to a DNA template for the isolated RNA comprising an intron RNA that is released in a cell thereby modulating the function of a target gene, wherein the isolated RNA does not contain a combination of a splice donor site that includes 5'-GU(A/G)AGU-3' and a splice acceptor site that includes 5'-CU(A/G)A(C/U)NG-3', and a cultivated cell thereof, classifiable in class 536, subclass 23.1.

III. Claims 13-15, drawn to an animal comprising the isolated RNA comprising an intron RNA that is released in a cell thereby modulating the function of a target gene, wherein the isolated RNA does not contain a combination of a splice donor site that includes 5'-GU(A/G)AGU-3' and a splice acceptor site that includes 5'-

CU(A/G)A(C/U)NG-3', classifiable in class 800, subclass 21.

IV. Claims 16-28, drawn to an animal comprising a DNA template for the isolated RNA comprising an intron RNA that is released in a cell thereby modulating the function of a target gene, wherein the isolated RNA does not contain a combination of a splice donor site that includes 5'-GU(A/G)AGU-3' and a splice acceptor site that includes 5'-CU(A/G)A(C/U)NG-3', classifiable in class 800, subclass 21.

V. Claim 21, drawn to a method of making an intron RNA comprising cultivated a cell containing an isolated RNA comprising an intron RNA that is released in a cell thereby modulating the function of a target gene, wherein the isolated RNA does not contain a combination of a splice donor site that includes 5'-GU(A/G)AGU-3' and a splice acceptor site that includes 5'-CU(A/G)A(C/U)NG-3', classifiable in class 435, subclass 6.

VI. Claim 22, drawn to a method of making an intron comprising cultivated a cell containing a DNA template for the isolated RNA comprising an intron RNA that is released in a cell thereby modulating the function of a target gene, wherein the isolated RNA does not contain a combination of a splice donor site that includes 5'-GU(A/G)AGU-3' and a splice acceptor site that includes 5'-CU(A/G)A(C/U)NG-3', classifiable in class 435, subclass 6.

VII. Claim 23, drawn to a method of modulating the function of a target gene in a cell comprising contacting said cell with an isolated RNA comprising an intron RNA that is released in a cell thereby modulating the function of a target gene, wherein the isolated RNA does not contain a combination of a splice donor site that includes 5'-GU(A/G)AGU-3' and a splice acceptor site that includes 5'-

CU(A/G)A(C/U)NG-3', classifiable in class 435, subclass 91.1.

VIII. Claim 24, drawn to a method of modulating the function of a target gene in a cell comprising contacting said cell with a DNA template for the isolated RNA comprising an intron RNA that is released in a cell thereby modulating the function of a target gene, wherein the isolated RNA does not contain a combination of a splice donor site that includes 5'-GU(A/G)AGU-3' and a splice acceptor site that includes 5'-CU(A/G)A(C/U)NG-3', classifiable in class 435, subclass 91.1.

IX. Claims 25-30, drawn to a composition comprising a chemokine and an isolated RNA comprising an intron RNA that is released in a cell thereby modulating the function of a target gene, wherein the isolated RNA does not contain a combination of a splice donor site that includes 5'-GU(A/G)AGU-3' and a splice acceptor site that includes 5'-CU(A/G)A(C/U)NG-3', classifiable in class 536, subclass 24.1.

X. Claim 31, drawn to a method of modulating the function of a target gene in a cell comprising contacting said cell with a composition comprising a chemokine and an isolated RNA comprising an intron RNA that is released in a cell thereby modulating the function of a target gene, wherein the isolated RNA does not contain a combination of a splice donor site that includes 5'-GU(A/G)AGU-3' and a splice acceptor site that includes 5'-CU(A/G)A(C/U)NG-3', classifiable in class 435, subclass 91.1.

XI. Claims 32-37, drawn to a composition comprising a chemokine and a DNA template for the isolated RNA comprising an intron RNA that is released in a cell thereby modulating the function of a target gene, wherein the isolated RNA does

not contain a combination of a splice donor site that includes 5'-GU(A/G)AGU-3' and a splice acceptor site that includes 5'-CU(A/G)A(C/U)NG-3', classifiable in class 536, subclass 23.1.

XII. Claim 38, drawn to a method of modulating the function of a target gene in a cell comprising contacting said cell with a composition comprising a composition comprising a chemokine and a DNA template for the isolated RNA comprising an intron RNA that is released in a cell thereby modulating the function of a target gene, wherein the isolated RNA does not contain a combination of a splice donor site that includes 5'-GU(A/G)AGU-3' and a splice acceptor site that includes 5'-CU(A/G)A(C/U)NG-3', classifiable in class 536, subclass 23.1.

XIII. Claims 39-49, drawn to a composition comprising one or more agents that induce RNA-mediated modulation of the function of two or more target genes in a cell, classifiable in class 536, subclass 24.5.

XIV. Claims 50-57, drawn to a method of modulating the function of genes in a cell comprising administering a composition comprising one or more agents that induce RNA-mediated modulation of the function of two or more target genes in a cell, classifiable in class 435, subclass 91.1.

Claims 1 and 7 links the isolated RNA compositions of claims 2-6 and 8. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claims, claims 1 and 7. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if

any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

Searching the inventions of Groups I and II together would impose a serious

search burden. The inventions of Groups I and II are unrelated, each from the other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the inventions of Groups I and II are unrelated and distinct because they are different molecules with different chemical and physical structures so that independent searches of the prior art would be required that would constitute a serious burden on the Examiner. For example, a search of the isolated RNA comprising an intron RNA of Group I would not necessarily encompass all of the art relevant to the DNA template for the isolated RNA comprising an intron RNA of Group II. Since a search of Group I would not encompass all the art relevant to Group II, the inventions are not coextensive. Since the search for Groups I and II are not entirely coextensive, it would be burdensome to search the inventions of these Groups together in one application. Thus, they are patentably distinct from each other.

Searching the inventions of Groups III and IV together would impose a serious search burden. The inventions of Groups III and IV are unrelated, each from the other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the inventions of Groups I and II are unrelated and distinct because they are different molecules with different chemical and physical structures so that independent searches of the prior art would be required that would constitute a serious burden on the Examiner. For example, a

search of the animal comprising an isolated RNA comprising an intron RNA of Group III would not necessarily encompass all of the art relevant to the animal comprising a DNA template for the isolated RNA comprising an intron RNA of Group IV. Thus, they are patentably distinct from each other. Since a search of Group III would not encompass all the art relevant to Group IV, the inventions are not coextensive. Since the search for Groups III and IV are not entirely coextensive, it would be burdensome to search the inventions of these Groups together in one application. Thus, they are patentably distinct from each other.

The Invention of Group I is related to the Invention of Group V as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the isolated RNA comprising an intron RNA of Group I can be used as an inhibitor of gene function in a method of modulating the function of a target gene, which is materially different than the method of making an intron of Group V. Furthermore, restriction is proper because the subject matter is divergent and non-coextensive and a search for one Group would not necessarily reveal art against the other Group. It is therefore a burden to search both of these inventions in a single application.

The Invention of Group II is related to the Invention of Group VI as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be

practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the DNA template for the isolated RNA comprising an intron RNA of Group II can be used as an inhibitor of gene function in a method of modulating the function of a target gene, which is materially different than the method of making an intron of Group VI. Furthermore, restriction is proper because the subject matter is divergent and non-coextensive and a search for one Group would not necessarily reveal art against the other Group. It is therefore a burden to search both of these inventions in a single application.

The Invention of Group I is related to the Invention of Group VII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the isolated RNA comprising an intron RNA of Group I can be used in a method of making an intron of, which is materially different than the method of modulating the function of a target gene in a cell of Group VII. Furthermore, restriction is proper because the subject matter is divergent and non-coextensive and a search for one Group would not necessarily reveal art against the other Group. It is therefore a burden to search both of these inventions in a single application.

The Invention of Group II is related to the Invention of Group VIII as product and process of use. The inventions can be shown to be distinct if either or both of the

following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the DNA template for the isolated RNA comprising an intron RNA of Group II can be used in a method of making an intron of, which is materially different than the method of modulating the function of a target gene in a cell of Group VIII. Furthermore, restriction is proper because the subject matter is divergent and non-coextensive and a search for one Group would not necessarily reveal art against the other Group. It is therefore a burden to search both of these inventions in a single application.

Searching the inventions of Groups V and VI together would impose a serious search burden. Although the methods of Groups V and VI are related because they involve a method for method of making an intron, they are patentably distinct from each other. Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to related methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: They employ different molecules with different chemical and physical structures so that independent searches of the prior art would be required that would constitute a serious burden on the Examiner. For example, a search of the method of making an intron RNA comprising cultivated a cell containing an isolated RNA comprising an intron RNA of Group V would not necessarily encompass all of the art relevant to the method of making an intron comprising cultivated a cell containing a DNA template for the isolated RNA comprising

an intron RNA of Group VI. They are materially distinct methods which differ in reagents used and criteria for success. Thus, they are patentably distinct from each other.

Searching the inventions of Groups VII and VIII together would impose a serious search burden. Although the methods of Groups VII and VIII are related because they involve a method of modulating the function of a target gene in a cell, they are patentably distinct from each other. Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to related methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: They employ different molecules with different chemical and physical structures so that independent searches of the prior art would be required that would constitute a serious burden on the Examiner. For example, a search of the method of modulating the function of a target gene in a cell comprising contacting said cell with an isolated RNA comprising an intron RNA of Group VII would not necessarily encompass all of the art relevant to the method of modulating the function of a target gene in a cell comprising contacting said cell with a DNA template for the isolated RNA comprising an intron RNA of Group VIII. They are materially distinct methods which differ in reagents used and criteria for success. Thus, they are patentably distinct from each other.

Searching the inventions of Groups I and IX together would impose a serious search burden. The inventions of Groups I and IX are unrelated, each from the other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use

together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the inventions of Groups I and IX are unrelated and distinct because they are different molecules with different chemical and physical structures so that independent searches of the prior art would be required that would constitute a serious burden on the Examiner. For example, a search of the isolated RNA comprising an intron RNA of Group I would not necessarily encompass all of the art relevant to the composition comprising a chemokine and an isolated RNA comprising an intron RNA of Group IX. Furthermore, Group IX further comprises a chemokine which is not a requirement of the other Group, Group I. Since the search for Groups I and IX are not entirely coextensive, it would be burdensome to search the inventions of these Groups together in one application. Thus, they are patentably distinct from each other.

Searching the inventions of Groups II and XI together would impose a serious search burden. The inventions of Groups II and XI are unrelated, each from the other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the inventions of Groups II and XI are unrelated and distinct because they are different molecules with different chemical and physical structures so that independent searches of the prior art would be required that would constitute a serious burden on the Examiner. For example, a search of the DNA template for the isolated RNA comprising an intron RNA of Group II would not necessarily encompass all of the art relevant to the composition comprising a

chemokine and the DNA template for the isolated RNA comprising an intron RNA of Group XI. Furthermore, Group XI further comprises a chemokine which is not a requirement of the other Group, Group II. Since the search for Groups II and XI are not entirely coextensive, it would be burdensome to search the inventions of these Groups together in one application. Thus, they are patentably distinct from each other.

The Invention of Group IX is related to the Invention of Group X as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the composition comprising a chemokine and the isolated RNA comprising an intron RNA of Group IX can be used in a method of making an intron of, which is materially different than the method of modulating the function of a target gene in a cell of Group X. Furthermore, restriction is proper because the subject matter is divergent and non-coextensive and a search for one Group would not necessarily reveal art against the other Group. It is therefore a burden to search both of these inventions in a single application.

The Invention of Group XI is related to the Invention of Group XII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the

instant case the composition comprising a chemokine and the DNA template for the isolated RNA comprising an intron RNA of Group XI can be used in a method of making an intron of, which is materially different than the method of modulating the function of a target gene in a cell of Group XII. Furthermore, restriction is proper because the subject matter is divergent and non-coextensive and a search for one Group would not necessarily reveal art against the other Group. It is therefore a burden to search both of these inventions in a single application.

The Invention of Group XIII is related to the Invention of Group XIV as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the composition comprising one or more agents that induce RNA-mediated modulation of the function of two or more target genes in a cell, of Group XIII can be used as a hybridization probe in a method of identifying gene expression, which is materially different than the method of modulating the function of a target gene in a cell of Group XIV. Furthermore, restriction is proper because the subject matter is divergent and non-coextensive and a search for one Group would not necessarily reveal art against the other Group. It is therefore a burden to search both of these inventions in a single application.

If Group I is elected, claims 2, 4-6, and 8 are subject to an additional restriction since they are not considered to be a proper genus/Markush. See MPEP 803.02 -

PRACTICE RE MARKUSH-TYPE CLAIMS - If the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require restriction. Since the decisions in In re Weber, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and In re Haas, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. In re Harnish, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.

Claims 2 specifically claims poly-pyrimidine tract sequences that include SEQ ID NO:2 or SEQ ID NO:3. Although the sequences claimed are both poly-pyrimidine tract sequences, the sequences are considered to be unrelated, since each sequence claimed is structurally and functionally independent and distinct for the following reasons: each poly-pyrimidine tract sequence has a unique nucleotide sequence. As such the Markush/genus of poly-pyrimidine tract sequences in claim 2 is not considered to constitute a proper genus, and are therefore subject to restriction. Claim 4 specifically claims splice donor site sequences that include SEQ ID NO:4, SEQ ID NO:5, 5'-AGGUAGAGU-3' or 5'-AGGUAAGU-3'. Although the sequences claimed are

each splice donor site sequences, the sequences are considered to be unrelated, since each sequence claimed is structurally and functionally independent and distinct for the following reasons: each splice donor site sequence has a unique nucleotide sequence. As such the Markush/genus of splice donor site sequences in claim 4 are not considered to constitute a proper genus, and are therefore subject to restriction. Claim 5 specifically claims splice acceptor site sequences that include SEQ ID NO:6, 5'-GGCUGCAGG-3', or 5'-CCACAGC-3'. Although the sequences claimed are each splice acceptor site sequences, the sequences are considered to be unrelated, since each sequence claimed is structurally and functionally independent and distinct for the following reasons: each splice acceptor site sequence has a unique nucleotide sequence. As such the Markush/genus of splice acceptor site sequences in claim 5 are not considered to constitute a proper genus, and are therefore subject to restriction. Claim 6 specifically claims branch site sequences that 5'-UACUAAC-3' or 5'-UACUUAUC-3'. Although the sequences claimed are each branch site sequences, the sequences are considered to be unrelated, since each sequence claimed is structurally and functionally independent and distinct for the following reasons: each branch site sequence has a unique nucleotide sequence. As such the Markush/genus of branch site sequences in claim 6 are not considered to constitute a proper genus, and are therefore subject to restriction. Furthermore, a search of more than one (1) of the poly-pyrimidine tract, splice donor site, splice acceptor site and branch site sequences claimed in claims 2, 4-6, and 8 presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more

than one (1) of the claimed sequence(s). In view of the foregoing, one (1) poly-pyrimidine tract, one (1) splice donor site, one (1) splice acceptor site and one (1) branch site sequence is considered to be a reasonable number of sequences for examination. Accordingly, applicants are required to elect one (1) poly-pyrimidine tract, one (1) splice donor site, one (1) splice acceptor site and one (1) branch site sequence from claims 2, 4-6, and 8. Note that this is not a species election.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is 571-272-0758. The examiner can normally be reached on 9 am - 5 pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

tcg
July 7, 2006